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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, 455, and 498

[CMS-6073-N2]

Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Revisions to the Provider Enrollment Moratoria Access Waiver Demonstration for Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Moratoria-Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Revisions of the waiver demonstration.

SUMMARY: This document announces revisions to the Provider Enrollment Moratoria Access Waiver Demonstration (PEWD) for Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies. The demonstration was implemented in accordance with section 402(a)(1)(J) of the Social Security Amendments of 1967 and, as revised, gives CMS the authority to grant waivers to the statewide enrollment moratoria on a case-by-case basis in response to access to care issues and previously denied enrollment applications because of statewide moratoria implementation, and to subject providers and suppliers enrolling via such waivers to heightened screening, oversight, and investigations.

DATES: The revisions to the waiver demonstration are effective [Insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Jung Kim, (410) 786-9370. News media representatives must contact CMS' Public Affairs Office at (202) 690-6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Social Security Act (the Act) provides CMS with tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), including the authority to place a temporary moratorium on provider enrollment in these programs, 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)). CMS uses quantitative and qualitative data to determine whether there is a need for a moratorium, such as reviewing whether the area under consideration for a moratorium has significantly higher than average billing per beneficiary or provider per beneficiary ratios. CMS first used its moratoria authority on July 30, 2013, to prevent enrollment of new Home Health Agencies (HHAs) in the Chicago, Illinois and Miami, Florida areas, as well as Part B ground ambulance suppliers in the Houston, Texas area (see the July 31, 2013 **Federal Register** (78 FR 46339)). These moratoria also applied to Medicaid and CHIP. CMS exercised this authority again on January 30, 2014, to extend the existing moratoria for 6 months and expand them to include HHAs in Fort Lauderdale, Florida; Detroit, Michigan; Houston, Texas; and Dallas, Texas; as well as Medicaid, CHIP and Medicare Part B ground ambulance suppliers in Philadelphia, Pennsylvania and nearby New Jersey counties (see the February 4, 2014 **Federal Register** (79 FR 6475)). Since the moratoria were expanded, they remained in place and were extended in 6-month intervals. On July 29, 2016, CMS extended the existing moratoria for 6 months and expanded them to statewide in the impacted states (see the August 3, 2016 **Federal**

Register (81 FR 51120)). The statewide moratoria have since been extended at 6-month intervals and to date, largely remain in place in all of the previously-mentioned locations.¹

Since initial implementation of the moratoria, CMS has monitored the program and identified several operational challenges. Because the moratoria were initially geographically defined by county, the moratoria did not prohibit existing providers and suppliers from opening a branch location in, or moving a currently-enrolled business into, a moratoria area. Moreover, CMS was unable to prevent existing providers and suppliers enrolled outside of a moratoria area from servicing beneficiaries within the moratoria area. In fact, CMS discovered providers and suppliers who were located several hundred miles outside of a moratorium area that were billing for services furnished to beneficiaries located within the moratorium area.

As noted previously, on July 29, 2016, CMS implemented statewide moratoria on newly enrolling HHAs in Medicare, Medicaid, and CHIP, and non-emergency ground ambulance suppliers in Medicare Part B, Medicaid, and CHIP in order to mitigate the vulnerabilities identified and described previously regarding the prior county-based moratoria. Concurrently, CMS implemented this Demonstration in order to improve methods for the investigation and prosecution of fraud, and to ensure that program integrity enforcement actions did not impact beneficiary access to care; in particular, all of the states impacted by the expanded statewide moratoria have rural areas that could be impacted by the statewide expansion. By implementing this Demonstration, CMS created a process that allows for need-based waivers to the moratoria in areas with access to care issues. Recently, CMS re-evaluated the continued need for statewide

¹ Effective July 29, 2016, CMS lifted the moratoria on Part B emergency ground ambulance suppliers in all locations. (81 FR 51120) In addition, effective September 1, 2017, CMS lifted the moratoria on Part B non-emergency ground ambulance suppliers in Texas. (82 FR 51274) These actions also applied to Medicaid and CHIP.

moratoria on the enrollment of new Part B, Medicaid, and CHIP non-emergency ground ambulance suppliers in New Jersey and Pennsylvania, and HHAs in Florida, Illinois, Michigan, and Texas, and determined that the conditions that caused CMS to implement the moratoria have not abated. As a result, on July 29, 2018 (see the August 2, 2018 **Federal Register** (83 FR 37747), we extended the statewide moratoria on Part B, Medicaid, and CHIP non-emergency ground ambulance suppliers and HHAs in the impacted states.

A. Operational Challenges

Since expanding statewide, a new statutory provision affecting the moratoria areas has taken effect. In December 2016, Congress enacted the 21st Century Cures Act (Cures Act). Section 17004 of the Cures Act provides authority to address issues of circumvention of the prior county-based moratoria by prohibiting payment for items or services furnished within moratoria areas by any newly enrolled provider or supplier that is of a provider or supplier type subject to the moratoria.

We believe it is necessary to maintain statewide moratoria and this Demonstration in Medicare, Medicaid, and CHIP in order to more effectively rectify the circumvention issue. As such, we must address a challenge we identified with carrying out the statewide moratoria and the existing Demonstration in light of the Cures Act requirement. The Demonstration provides an opportunity for providers and suppliers otherwise subject to the moratoria to enroll and furnish services within a moratorium area if CMS determines that there are access to care issues in a particular geographic area. However, the Cures Act provision prevents payments to newly enrolled providers and suppliers subject to the moratoria for items and services furnished in moratoria areas. This includes those providers and suppliers enrolled under the Demonstration. This Cures Act provision became effective for such items and services furnished on or after

October 1, 2017. To continue to avoid potential patient access to care issues and to continue a process to test whether allowing for targeted anti-fraud activities through heightened screening of providers and suppliers enrolling through the Demonstration will improve methods for the investigation and prosecution of fraud under section 402(a)(1)(J) of the Social Security Amendments of 1967, CMS is revising the Demonstration to waive the requirements of section 17004 of the Cures Act for the providers and suppliers enrolled under the Demonstration.² With this revision, providers and suppliers enrolled under the Demonstration will be able to receive Medicare, Medicaid, and/or CHIP payment for items and services furnished within the provider's or supplier's approved service area for the Demonstration.

B. Expanded Access to the Demonstration

The regulation at 42 CFR 424.570(a)(1)(iv) provides that a temporary enrollment moratorium does not apply to any enrollment application that has been approved by the Medicare Administrative Contractor (MAC) but not yet entered into PECOS at the time the moratorium is imposed. During the time period when the moratoria was county-based, some providers and suppliers spent a substantial amount of time and considerable resources preparing for enrollment in states subject to the prior county-based moratoria only to have their Form CMS-855 applications denied near the end of the enrollment process because of the sudden imposition of a statewide moratorium. This has been especially problematic for HHAs—(1) whose Form CMS-855A applications had been recommended for approval by the MAC; (2) that had successfully completed a state survey; and (3) whose applications and survey results had been forwarded by the state to the CMS regional office for final review.

² The Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act under section 402(b) of Pub. L. 90-248, (42 U.S.C. 1395b-1(b)).

As a result, CMS is further revising the Demonstration to include two different options for eligibility: (1) the existing option requiring that the provider or supplier demonstrate that access to care issues exist; or (2) the new alternative option requiring that the provider or supplier establish that it had submitted an enrollment application prior to implementation of the moratorium that was denied as a result of implementation of such moratorium. This alternative requirement applies to the July 29, 2016 statewide moratoria and any moratoria that are implemented subsequent to, and for the duration of, this demonstration. Thus this revision will allow CMS to approve individual waivers to a statewide moratorium due to providers or suppliers demonstrating that access to care issues exist, or for providers and suppliers that had submitted an enrollment application prior to implementation of a moratorium on July 29, 2016, or later, that was denied by their relevant MAC as a result of implementation of such moratoria. Providers and suppliers who meet either of these criteria will be subject to the heightened screening, oversight, and restrictions of the revised Demonstration. These two options for eligibility will allow additional opportunities for providers and suppliers to enroll under the revised Demonstration. This will better allow CMS to test whether conducting targeted anti-fraud activities through heightened screening of enrolling providers or suppliers, in conjunction with increased oversight and other restrictions, will improve methods for the investigation and prosecution of fraud under Section 402(a)(1)(J) of the Social Security Amendments of 1967. As such, for purposes of this Demonstration, CMS is waiving the regulatory requirement in 42 CFR 424.570(a)(1)(iv), described previously.³

³ The Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act under section 402(b) of Pub. L. 90-248, (42 U.S.C. 1395b-1(b)).

C. Enrollment Effective Date Flexibilities

Regardless of the reason a provider or supplier qualifies for the Demonstration, CMS is also revising the Demonstration to provide additional discretion regarding the effective date of new billing privileges in order to better address any access to care concerns that do arise. CMS is waiving the regulatory requirement in 42 CFR 424.520(a) and (d) governing the effective date of new billing privileges for certified providers and ambulance suppliers, respectively, so as to allow CMS to evaluate and assign effective dates depending on whether access to care issues exist in the service area.⁴

D. Summary

As described in greater detail in section II. of this document, because CMS sees a high incidence of fraud in the moratoria areas, extensive screening and review of providers and suppliers newly enrolling under the Demonstration will be coupled with an earlier review of claims and other investigations and prosecutions of fraud with respect to such providers and suppliers. The revised Demonstration will also support statewide moratoria by addressing the moratoria circumvention issues that surfaced throughout the prior county-based moratoria and providing waivers to the moratoria to ensure that beneficiary access to care is not adversely impacted. Approval of a waiver would be based primarily on either the provider or supplier demonstrating an access to care issue exists or that the provider or supplier submitted an enrollment application prior to implementation of a moratorium on July 29, 2016, or later that was denied as a result of implementation of such moratorium, and secondarily on passing the enhanced screening measures in the approved service area.

⁴ The Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act under section 402(b) of Pub. L. 90-248, (42 U.S.C. 1395b-1(b)).

A finding of fraud risk in Medicare typically means that the risk also exists in Medicaid and CHIP, as recognized by section 1902(a)(39) of the Act, which requires state Medicaid agencies to terminate the participation of any individual or entity if such individual or entity is terminated under Medicare or any other state's Medicaid or CHIP program. Moreover, access to care issues are of equal concern in the context of Medicaid and CHIP. As a result, CMS will also implement the revised Demonstration in Medicaid and CHIP.

II. Demonstration Design and Duration

This revised Demonstration will continue to support the existing statewide moratoria on HHAs in Medicare, Medicaid, and CHIP, and non-emergency ground ambulance suppliers in Medicare Part B, Medicaid, and CHIP. This revised Demonstration will allow a provider or supplier to submit a Provider Enrollment Moratoria Access Waiver (waiver) application that, if approved, will exempt such provider or supplier from the moratorium in designated geographic areas. The waiver application for Medicare enrollment will be reviewed by CMS, and this review will include heightened screening measures. The waiver application for Medicaid and CHIP will be reviewed by the relevant State Medicaid Agency. If the provider or supplier receives a waiver, restrictions may be imposed on such provider's or supplier's service area to limit the number of new providers or suppliers in a location that is already oversaturated with particular providers and/or suppliers. This restriction will be based on the saturation of providers or suppliers and the number of beneficiaries in the counties where the provider or supplier proposes to operate. Extensive evaluations of providers and suppliers seeking to enroll through this demonstration will be coupled with proactive reviews of submitted claims on an ad hoc basis, beginning within the first 30 to 60 days of enrollment and continuing for the first year of

enrollment, as well as increased investigations with referral to law enforcement as appropriate, for newly enrolled and existing providers.

A. Medicare Implementation

All waiver applications, with the appropriate CMS-855⁵ enrollment application form and supporting documentation, should be submitted electronically to a designated mailbox: ProviderEnrollmentMoratoria@cms.hhs.gov. Upon receipt of the applicable CMS-855 application, waiver application, all supporting documentation, and payment of the enrollment application fee, CMS will review for completeness and, within 30 days, will respond with confirmation of receipt or in the case of an incomplete application, rejection. As part of the Demonstration, CMS will review the applicant's affiliations to include: (1) a 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization; (2) a general or limited partnership interest that an individual or entity has in another organization; (3) an interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operations of another organization, either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization; (4) an interest in which an individual is acting as an officer or director of a corporation; (5) any reassignment relationship. In section 5 of the Waiver Application⁶, we require providers and suppliers to report affiliations with entities and individuals that: (1) currently have uncollected debt to Medicare, Medicaid, or CHIP; (2) have been or are subject to a payment suspension under a federal health care program or subject

⁵ CMS 855 is the Medicare provider and supplier enrollment application and may be found at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.html>

⁶ The Waiver Application may be found at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html>

to an Office of Inspector General (OIG) exclusion; or (3) have had their Medicare, Medicaid, or CHIP enrollment denied or revoked. Should such an affiliation be reported or discovered, CMS could deny the provider's or supplier's PEWD application if CMS determines that the affiliation poses an undue risk of fraud, waste, or abuse. As part of the review to determine undue risk, CMS will consider the duration of the applicant's relationship with the affiliated entity or individual, determine whether the affiliation still exists or how long ago it ended, the degree and extent of the affiliation, and reason for termination of the affiliation if applicable. CMS may also deny a provider's or supplier's PEWD application if CMS determines that the provider or supplier is currently revoked from Medicare, Medicaid, or CHIP under a different name, numerical identifier, or business identity. To minimize provider burden the "look-back" period for disclosure of affiliations will be within the previous 5 years. However, there will be no cut-off or specific "look-back" period for when the disclosable event occurred or was imposed.

Should CMS receive more than one application for a particular geographical area, and the acceptance factor is based on access to care, the applications will be prioritized by order of receipt until the access to care concern is alleviated. Should CMS receive more than one application for a particular geographical area, and the acceptance factor is that enrollment applications were denied because of implementation of moratoria, all applications will be prioritized and processed in the order of receipt. Should CMS receive applications for a particular geographical area from a provider or supplier seeking to demonstrate an access to care issue and from another provider or supplier whose enrollment application was denied as a result of implementation of moratoria, the application from the provider or supplier whose enrollment application was denied due to the implementation of moratoria will be prioritized. An application will not be considered received until it is complete, including fingerprinting.

Subsequently, CMS will have 90 days from initial receipt to review each application and communicate a decision to the provider or supplier.

Once a complete application is received, the determining factor for waiver approval under this revised Demonstration, and the first step in application review, will either be (1) a determination regarding beneficiary access to care; or (2) verification that the provider or supplier had submitted an enrollment application prior to implementation of a moratorium on July 29, 2016, or later, that was denied as a result of implementation of such moratorium. With respect to providers and suppliers seeking a waiver based on access to care issues, the determination will be primarily based upon an evaluation of provider and supplier saturation, provider or supplier to beneficiary ratios, and claims data; this review will be supplemented with any access to care information that the provider or supplier has provided. As a requirement of the application, the provider or supplier will be required to submit detailed access to care information that demonstrates whether an access to care issue exists in the counties where the provider or supplier is attempting to enroll. In 2016, CMS released saturation data to the public. This data set, located at <https://data.cms.gov/market-saturation>, includes saturation data for the nation and identifies states that are impacted by moratoria. This data gives both states and the public detailed information relevant for access to care justification. Additionally, we are expecting anecdotal data from the applicants to support that an access to care issue exists, which should not subject applicants to the unnecessary burden of performing extensive analyses. CMS will evaluate the provider- or supplier-generated information and compare it with statistical analysis data that is generated internally by CMS to determine whether an access to care issue exists in the identified area.

If CMS determines that a beneficiary access to care issue does not exist in the counties where the provider or supplier proposes to operate, the application will be rejected and the application fee will be refunded. Upon rejection, the provider or supplier may submit a new application at any time. If any subsequent application demonstrates an access to care issue, then CMS may move forward with processing the application.

For those providers or suppliers seeking a waiver because their enrollment application was denied as a result of implementation of a moratorium, if CMS cannot verify the denial, the application will be rejected and the application fee will be refunded. Upon rejection, the provider or supplier may submit a new application at any time. If for any subsequent application CMS is able to verify that the provider or supplier had submitted an enrollment application prior to implementation of a moratorium that was denied as a result of such moratorium, then CMS may move forward with processing the application.

When CMS determines that there is a beneficiary access to care issue in the counties where the provider or supplier has proposed to enroll, or when CMS verifies that the provider or supplier had submitted an enrollment application prior to implementation of a moratorium that was denied as a result of implementation of such moratorium, CMS will move forward with processing the application. CMS will utilize the ownership information in the submitted CMS-855 application, in conjunction with the revised Demonstration, to perform numerous screening measures, which will include the following:

- License verification
- Background investigations including evaluation of affiliations
- Federal debt review
- Credit history review

- Fingerprint-based criminal background checks (FCBC) of persons with a 5 percent or greater direct or indirect ownership interest, partners, and managing employees.

- Enhanced site visits
- Ownership interest verification
- Evaluation of past behavior in other public programs

Providers and suppliers who do not pass the heightened screening requirements will receive a letter stating that their application has been denied and indicating the specific reason(s) for denial. The provider or supplier may submit an appeal to CMS within 15 days of the date of denial. The appeal must specifically address the reason(s) for denial and detail the action(s) taken to resolve any deficiency. CMS will evaluate the appeal and process or deny the application as appropriate. If a provider's or supplier's application is denied, the application fee will not be refunded. Further, if a provider or supplier is denied for a reason under 42 CFR 424.530(a), the provider or supplier may not reapply for a waiver under the Demonstration.

Providers and suppliers who are recommended for enrollment under the Demonstration will be advised that their respective CMS-855 applications are being forwarded to the Medicare Administrative Contractor (MAC) for further processing. The MAC will process the application and determine whether enrollment is appropriate based on all current policies and procedures. All applicants who are enrolled through the Demonstration will be subject to all Medicare policies and regulations, including revalidation within 5 years of initial enrollment, in addition to the heightened oversight that is implemented through the Demonstration.

The Act includes requirements regarding provider enrollment and oversight for the Medicare and Medicaid Programs. Among other provisions, section 1866(j)(3)(A) of the Act

allows for up to a 1-year provisional period of enhanced oversight of newly enrolled providers of services and suppliers, which may be implemented through program instruction. During this Demonstration, CMS will utilize this authority and may revoke a provider's or supplier's Medicare billing privileges if the enhanced oversight identifies grounds for such revocation.

As an enhanced oversight measure, providers or suppliers that are approved to enroll in the Demonstration because of a determination that access to care issues exist in the areas where they proposed to enroll will be given a specific need-based geographic area, by county, in which they are approved to operate. For those providers or suppliers who are approved on the basis of an access to care issue, should CMS find that the access to care limitation extends beyond the counties that were initially proposed by the provider or supplier, CMS may accordingly request that the provider or supplier expand the area of operation. Providers and suppliers that are approved to enroll in the Demonstration because they had submitted an enrollment application prior to implementation of a moratorium that was denied as a result of implementation of such moratorium will be allowed to service locations listed in the enrollment application that they submit with their waiver application. However, as discussed earlier in section II of this document, restrictions may be imposed on the service area of a provider or supplier approved to enroll in the Demonstration in order to limit the number of new providers or suppliers in a location that is already oversaturated with particular providers and/or suppliers. This will be applicable to providers or suppliers that are approved to enroll in the Demonstration because of a determination that access to care issues exist or because they had submitted an enrollment application prior to implementation of a moratorium that was denied as a result of implementation of such moratorium.

Providers or suppliers enrolling under the Demonstration may not bill beneficiaries for services furnished outside of the approved service area, and claims for services furnished outside of the approved service area will be denied. Additionally, in response to fraud trends, CMS may perform medical review of claims submitted, including an evaluation of any prior relationships between the provider or supplier and the beneficiary and whether the services were medically necessary. Other reviews may be performed if deemed necessary. CMS will continue the enhanced oversight throughout the revised Demonstration, billing patterns will be monitored through the Fraud Prevention System (FPS), and any abuse of billing privileges may result in revocation of Medicare billing privileges.

The combined goal of the statewide moratoria and the revised Demonstration outlined herein is to address beneficiary access to care issues, while targeting fraud, waste, and abuse. Success of this revised Demonstration is contingent upon an increase in oversight and enforcement in all six current moratoria states. This oversight will be provided using existing tools, as well as those created through this revised Demonstration, by both CMS and CMS' law enforcement partners. Under this revised Demonstration, CMS will share applicable data with law enforcement partners to aid in the investigation and prosecution of fraud.

Through quarterly data evaluations, CMS will continue to carefully monitor potential access to care issues that could develop in the moratoria states. Additionally, CMS will respond to any access issue identified and brought to our attention outside of the quarterly review.

B. Increased Investigation and Prosecution

As a measure to enhance our oversight in these high risk areas, the revised waiver application process will include a more robust evaluation of the provider/supplier, including license verification, detailed background checks, fingerprinting, comprehensive site visits,

ownership interest verification, and evaluation of past behavior in other public programs, such as Medicaid and CHIP, as applicable. The revised waiver application will also require the provider or supplier to submit a specific county-based enrollment justification based on access to care, the boundaries of which CMS would confirm and ultimately enforce, with the exception of providers and suppliers that had an enrollment application denied by their relevant MAC as a result of implementation of a moratorium. As detailed elsewhere in this document, once a provider or supplier is enrolled pursuant to a waiver, that provider or supplier would be subjected to augmented investigation and monitoring in order to confirm continued compliance with Medicare requirements.

Throughout the course of the Demonstration, CMS will work with all of its partners to identify fraudulent providers and suppliers and will take administrative action to remove such providers and suppliers from the Medicare program. Additionally, within 30 to 60 days of a provider's or supplier's enrollment pursuant to a waiver, CMS will perform proactive monitoring and oversight of such provider or supplier, including proactive examination of claims data and investigation of billing anomalies. Further, CMS will prioritize Demonstration-related investigations and will make referrals to appropriate law enforcement partners, including Department of Justice (DOJ), Office of Inspector General (OIG), and state law enforcement agencies, for prosecution of fraud.

C. Medicaid and CHIP Implementation

In addition to the Medicare program, this revised Demonstration will also apply to Medicaid and CHIP. The states will administer the Medicaid and CHIP Demonstration and will independently evaluate access to care. All Demonstration-related processes, including but not limited to heightened screening, enrollment, denials, and appeals, will be operationalized by the

state Medicaid and CHIP agencies in accordance with federal and state regulations and guidance. The states will make recommendations to CMS regarding when a provider should be enrolled based on access to care issues, and must wait for CMS concurrence prior to enrolling a provider under the Demonstration. CMS will evaluate all recommendations within 30 days of receipt, and will advise the state as to whether or not CMS concurs with the recommendation to move forward in the enrollment process. CMS encourages states to use their discretion when determining whether to approve a waiver for any provider who had submitted an application prior to implementation of a moratorium that was denied as a result of implementation of such moratorium. States that choose to apply waivers in this manner should do so consistently for all providers who were denied as a result of the moratorium. States are not required to seek CMS approval of their waiver process. Additionally, states will not be required to seek approval from CMS to deny a waiver application. If a provider receives an enrollment waiver from Medicare, that provider will be eligible to enroll in Medicaid or CHIP without further review by the states. However, if a provider receives a Medicaid or CHIP waiver, the provider must separately apply for a waiver with Medicare.

As provided in 42 CFR 455.470, a state Medicaid agency is not required to impose a moratorium if the state Medicaid agency determines that imposition of a temporary moratorium would adversely affect beneficiaries' access to medical assistance and notifies the Secretary in writing of this determination.

D. Duration of the Demonstration

The Demonstration commenced on July 29, 2016 and was to continue for a period of 3 years, or until the moratoria are lifted, whichever occurs first. However, CMS is extending the Demonstration an additional 2 years, for a total of 5 years, through July 28, 2021. Since the

commencement of the demonstration, CMS thus far has collected limited data on which to evaluate the effectiveness of the demonstration. We expect that the extension to 5 years will allow more providers and suppliers to enroll under the Demonstration, thus providing CMS with more data on which to evaluate the Demonstration's effectiveness. Should CMS choose to lift all of the moratoria prior to July 28, 2021, we will not continue the Demonstration.

E. Demonstration Conclusion

CMS will utilize the Demonstration as an opportunity to observe the statewide moratoria and heightened application review effectiveness over the course of 5 years, or until the moratoria are lifted, whichever occurs first. Should the Demonstration prove to be a useful tool, we hope to consider continuing and expanding the most successful aspects outside the context of a demonstration. The enhanced oversight exercised as part of the Demonstration will also allow us to identify trends and vulnerabilities in the moratoria states and make program adjustments to accommodate fraud schemes as they transform over time.

Concurrent with the Demonstration, CMS will continue to assess and improve current regulatory requirements for HHAs, ambulance suppliers, and other provider/supplier types that pose a high risk to the Medicare program. In the absence of additional rulemaking, any enrollments that occur as part of the Demonstration, assuming that the enrolled providers or suppliers are in compliance with all Medicare requirements, will convert to standard enrollments without geographical billing restrictions at the end of the Demonstration.

CMS recognizes that a moratorium is a temporary tool that we have implemented in order to conduct targeted investigations and related enforcement actions in high saturation, high risk areas. As required under our regulations, we will re-evaluate the continued need for the moratoria every 6 months and may lift the moratoria at any time if the Secretary determines that

the moratoria are no longer needed, or the circumstances warranting the imposition of moratoria have abated or CMS has implemented program safeguards to address the program vulnerability, among other rationale.⁷ We will monitor the moratoria areas to determine if it is appropriate to lift all moratoria (and thus end the Demonstration), including the following criteria:

- Beneficiary access to care
- Provider or supplier growth rates
- The number of providers or suppliers per beneficiary
- Provider/supplier saturation
- Churn rate – the rate of providers/suppliers entering and exiting the program
- Claims paid per beneficiary
- Enforcement actions, including: revocations, denials, investigations, and referrals to

law enforcement and other related activities.

IV. Collection of Information Requirements

A. Background

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

⁷ 42 CFR 424.570

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). This is covered under OMB control number 0938-1313.

B. Burden Estimate (Hours and Wages)

1. Paperwork Burden Estimate (Hours)

The provider and supplier burden associated with completion of the waiver form is estimated at 6 hours per form. This will include the following time burden per form:

- 2 hours for completion of fingerprint-based criminal background check (FCBC)
- 2 hours for completion of access to care assessment
- 1.5 hours for completion of form
- 0.5 hours for completion of other miscellaneous administrative activities

There will be variation to this estimate based on proximity to a fingerprinting office as well as the complexity of the data that the provider or supplier elects to submit. To assist with completion of the access to care assessment, CMS has HHA and ambulance saturation data available at <https://data.cms.gov/market-saturation>.

CMS estimates 30 new applicants requesting waivers for a total of 180 burden hours annually. Additionally, the provider or supplier will have the additional burden associated with

completion of the CMS-855, which is required for enrollment into Medicare. This burden is covered under OMB control number 0938-0685.

2. Paperwork Burden Estimate (Costs)

This waiver form will be completed by providers and suppliers seeking a waiver to enroll in a moratorium area. The cost burden is estimated at \$27.60 (\$13.80 base pay) an hour for completion of access to care analysis and miscellaneous administrative activities, totaling \$69.00 per application, equaling \$2,070.00 annually. The cost burden is estimated at \$188.50 (\$94.25 base pay) an hour for the owner to obtain fingerprints and complete the waiver form totaling \$659.75 per application, equaling \$19,792.5 annually. Estimated annual burden for 30 newly enrolling applicants totals \$21,862.5. To derive average costs, we used data from the Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm#31-0000 for healthcare support occupations and <http://www.bls.gov/oes/current/oes111011.htm> for chief executives.) Hourly wage rates include the costs of fringe benefits (calculated at 100 percent of salary) and the adjusted hourly wage.

C. Response to Comments

We have submitted a copy of the **Federal Register** document to OMB for its review of the document's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit CMS' Web site at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index.html>, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the ADDRESSES section of this document and identify the document's filecode (CMS–6073-N2) the ICR's CFR citation, CMS ID number, and OMB control number.

V. Waiver Authority

Under section 402(b) of Pub. L. 90-248, (42 U.S.C. 1395b-1(b)), certain requirements of the Act and implementing regulations would be waived to the extent necessary to implement this demonstration.

Specifically, the authorities CMS is seeking to waive under this revised Demonstration include the following:

- Waiver of section 1866(j)(7)(C) of the Act, which was added by section 17004 of the 21st Century Cures Act. Effective for items and services furnished on or after October 1, 2017, the provision prohibits payment for items and services furnished within a temporary moratorium area by providers or suppliers who enroll after the effective date of such moratorium and who are within a category of providers and suppliers subject to such moratorium. We will allow payment to be made to providers and suppliers who enroll under the Demonstration and furnish items and services within a moratorium area, including those who were approved prior to this revised Demonstration.

- Waiver of § 424.570(a)(1)(iv) and (c). This regulation establishes moratoria rules for Medicare, Medicaid, and CHIP. Specifically, we will: (1) exempt providers and suppliers from the moratoria if they submitted an application to their MAC prior to July 29, 2016 that was denied as a result of implementation of statewide moratoria; and (2) exempt providers and suppliers from any future moratoria if they have submitted an application to their MAC prior to

the implementation date of that moratoria, without regard to provider type or geographic location. This waiver will be applicable to any moratoria that are implemented subsequent to, and for the duration of, this demonstration.

- Waiver of § 424.520(a) and (d), which establishes specific effective date requirements for certified providers and ambulance suppliers, respectively. This waiver will allow CMS to establish the effective date for a provider or supplier depending on whether access to care issues exist in the service area.

The authorities CMS previously waived under the original Demonstration, which we will continue to waive under the revised Demonstration, include the following:

- Waiver of §§ 424.518(c) and (d) and 455.434(a), which describe the fingerprinting rules for enrollment in Medicare, Medicaid and CHIP.⁸ This waiver involves expanding the existing regulatory authority in two ways: (1) to include ambulance suppliers requesting a waiver under the Demonstration within the categories of providers and suppliers to which the FCBC requirements apply; and (2) to include managing employees within the associated individuals subject to an FCBC when the provider or supplier seeks to enroll pursuant to a waiver under the Demonstration. Additionally, CMS intends to modify the authority that currently requires denial or revocation of providers or suppliers who fail to submit fingerprints, to instead specify that a waiver application will be rejected if the provider or supplier fails to submit the required fingerprints within 30 days.

⁸ According to 42 CFR 457.990, the enrollment screening requirements applicable to providers enrolling in Medicaid apply equally to those enrolling in CHIP.

- Waiver of 1866(j)(3)(B) of the Act, which requires program instruction or regulatory interpretation in order to implement section 1866(j)(3) of the Act, Provisional Period of Enhanced Oversight for New Providers of Services and Suppliers. CMS intends to implement the requirements of section 1866(j)(3) of the Act for purposes of this Demonstration and in the absence of regulation or other instruction in order to allow for a 1-year period of enhanced oversight of newly enrolling providers and suppliers under this Demonstration.

- Waiver of section 1866(j)(8) of the Act and the regulations at 42 CFR 424.545, 42 CFR part 498, subparts D and E, and 42 CFR 405.803(b), which allow a provider or supplier the right to request a hearing with an administrative law judge and the Department Appeals Board in the case of denial. Under this Demonstration, denials of applications for a waiver may be appealed at a CMS level only, and any applicant to the Demonstration will waive their right to further appeal.

- Waiver of 1866(j)(7) of the Act and the regulations at 42 CFR 424.570 and 455.470, which specify that the moratoria must be implemented at a provider or supplier type level, in order to allow a case-by-case waiver process to moratoria.

Dated: August 6, 2018.

Seema Verma

Administrator,

Centers for Medicare & Medicaid Services.

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